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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,136	01/07/2004	Kevin Edward Henegar	01238.US1	4433

25533 7590 12/13/2004

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EXAMINER	
FORD, ALLISON M	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/753,136	HENEGAR, KEVIN EDWARD	
	Examiner	Art Unit	
	Allison M Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☒ Claim(s) *4 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Claims 1-6 are pending in the current application.

Priority

It appears priority was intended to be claimed to provisional application 60/439,953, filed Jan 14, 2003, as stated in the first line of the specification. However, reference to the provisional application is missing on the Oath or Declaration under the section for provisional applications under 35 USC 119(e).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because priority under 35 USC §119(e) is claimed to the current US application, US 10/753,136. Priority should be claimed to provisional application 60/439,953, filed Jan 14, 2003.

Specification

In the specification applicant states: "The man skilled in the art can readily determine what proportion of pancreatin relative to substrate to use, based upon the purity level of the pancreatin, and the speed of reaction desired" (Pg 4, ln 7-9). It would be preferable to use the phrase, "One skilled in the art..." in place of, "The man skilled in the art," women can make this optimization determination as well.

Claim Objections

Though it is not grounds for an indefiniteness rejection, it is confusing why applicant chose to designate the steps 1a) through 4a) in claim 3, yet, did not continue this denotation as steps 5a) through 7a) in claim 4, or in claim 6. It would be preferable, for purposes of clarity, to make all steps in corresponding claims, have the same denotation, especially in claim 6.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claims 1 and 5 are directed to a process for the preparation of (1S, 4R) 1-acetoxy-4-hydroxycyclopent-2-ene. Step 3, in both claims 1 and 5, of the process requires the water content of the solution to be adjusted so that the water is 5-7% by weight relative to pancreatin. It is unclear what is meant by the water is 5-7% by weight relative to pancreatin. Because the pancreatin and water are already in solution with *cis*-1,4-dihydroxycyclopent-2-ene, vinyl acetate, in tetrahydrofuran it is unclear if the water is 5-7% (w/w) of the solution, or if the water is 5-7% (w/w) of the pancreatin only. The phrase "relative to pancreatin" makes the claim unclear and therefore indefinite. Claim 2 has the limitation of claim 1 and therefore is rejected on the same basis.

Applicant's claims 2 and 4 are directed to a process for the preparation of (1S, 4R) 1-acetoxy-4-hydroxycyclopent-2-ene. Step 5, in both claims 2 and 4, of the process require concentrating the reaction mixture at 20-50°C bath temperature and 20-60 mm pressure. The units of pressure is not clear, it appears it should read 20-60 mm Hg pressure, as is commonly used in the sciences as a unit of measure of pressure. Examination was conducted as such.

Applicant's claims 1-6 are directed to a process for the preparation of (1S, 4R) 1-acetoxy-4-hydroxycyclopent-2-ene. Step 4 of claims 1 and 5, and step 4a of claims 3 and 6 require the reaction to be maintained at a temperature of -40^0C to $+40^0$C, preferably -5^0C to $+10^0$C with stirring until the reaction is substantially complete. The term preferably is indefinite because it is unclear whether the 'preferable' embodiments are required as part of the claimed invention. Furthermore, 'preferably' is an indefinite term because it has to do with individual perception, it is therefore not clear to whom the temperature range of -5^0C to $+10^0$C is preferable. Claim 2 has the limitations of claim 1, claim 4 has the limitations of claim 3 and thus both are rejected on the same basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Theil et al (*Liebigs Ann Chem,* 1991).

Theil et al teach a process for the preparation of (1S, 4R) 1-acetoxy-4-hydroxycyclopent-2-ene (Formula 3a, See Pg 195 Scheme 1), comprising mixing pancreatin, *cis*-1,4-dihydroxycyclopent-2-ene (*meso*-diol, Formula 1, See Pg 195, Scheme 1), vinyl acetate, and triethylamine in tetrahydrofuran and stirring for approximately 2.5 hours until the *cis*-1,4-dihydroxycyclopent-2-ene was completely consumed, indicating the reaction was complete (See Pg. 199, col. 2). The monoacetate (1S, 4R) 1-acetoxy-4-hydroxycyclopent-2-ene (Formula 3a) was obtained. The procedure was carried out at room temperature, 25°C (See Pg. 199, col. 2). The pancreatin was obtained from Fa. Belger, Kleinmachnow, GDR, it was determined to have a water content of 5.4%, by Karl Fisher titration (See Pg 197, col. 2);

therefore there was no need to adjust the water content of the mixture relative to pancreatin, as the water content has been inherently adjusted to the claimed level (Claims 1 & 3). Therefore the reference anticipates the claimed subject matter.

Claim Rejections – 35 USC § 103

Claims 1 & 3 are rejected under 35 U.S.C. 103(a) as obvious over Lapitzkaja et al (German Patent 293 136), in view of Theil et al (*Liebigs Ann Chem,* 1991).

Lapitzkaja et al teach a process for the preparation of (4S, 1R) 1-acyloxy-4-hydroxycyclopent-2-ene, comprising mixing pancreatin, *cis*-1,4-dihydroxycyclopent-2-ene, vinyl acetate, and triethylamine in tetrahydrofuran; maintaining the reaction at 25^{0}C with stirring for 2.5 hours. Lapitzkaja et al chose to isolate the (4S, 1R)-4-acyloxy-1-hydroxycyclopent-2-ene (Formula I) enantiomer; however, one of ordinary skill in the art knows the reaction formed a racemic mixture that also included the (1S, 4R)-1-aceloxy-4-dihydroxycyclopent-2-ene enantiomer. Lapitzkaja et al do not specify the acyloxy group of the diacetyl esters, but because Lapitzkaja et al used *cis*-1,4-dihydroxycyclopent-2-ene as the starting substrate, and performed the same steps as in the current application, it is clear that the final racemic mixture included (4S, 1R) 4-acetoxy-1-hydroxycyclopent-2-ene and (1S, 4R)-1-acetoxy-4-hydroxycyclopent-2-ene.

Lapitzkaja et al is silent on the water content of the pancreatin used. It appears the pancreatin used by Lapitzkaja et al had a water content of 5-7% by weight, or was adjusted to have a water content of 5-7% by weight. However, even if the pancreatin used by Lapitzkaja et al did not have a water content of 5-7% by weight, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pancreatin with 5-7% water content, by weight, or to adjust the water content to 5-7% by weight before or after mixing the reaction. One of ordinary skill in the art would have been motivated to

use pancreatin with a water content of 5-7%, or adjust the water content of pancreatin to 5-7% before or after mixing, because Theil et al teaches success using pancreatin with a water content of 5.4% (See Theil et al, Pg 197, col. 2); and applicant submits that the water content can be adjusted either before or after mixing the components of the composition with no difference in effect. One would have expected success using pancreatin with a water content of 5-7% because Theil et al teaches success forming (1R, 4S) 1-acetoxy-4-hydroxycyclopent-2-ene from the said ingredients using pancreatin with a water content of 5.4%. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made (Claims 1 & 3).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER